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Section 7- 510k Summary

7.1 Statement This 510k summary is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

7.2 Submitter

Smith and Nephew, Inc.
Endoscopy Division
160 Dascomb Rd.
Andover, Ma. 01810

7.3 Company Contact

Tedd Gosian
Clinical/ Regulatory Manager
(508) 261-3771

7.4 Device Name

Proprietary Name: Smith & Nephew HAPLA Interference Screw
Common Name: HAPLA Interference Screw
Classification Name:

7.5 Predicate Legally Marketed Devices

- Smith & Nephew BioRCI Screw (K984320)
- Arthrex PLA Screw (K971358)
- Linvatec BioScrew (K973758)

7.6 Device Description The Smith & Nephew HAPLA Interference Screw is essentially identical to the BioRCI Screw described in K992396. The HAPLA Interference Screw is a cannulated, sterile, single-use bone screw made of an HAPLA Interference homopolymer blend derived from Polylactic acid (PLA) and hydroxylapatite.

7.7 Indications for Use The Smith & Nephew HAPLA Interference Screw is indicated for fixation of bone-tendon-bone or soft tissue grafts during anterior / posterior cruciate ligament reconstruction surgery.

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7.8 Substantial Equivalence

The Smith & Nephew HAPLA Interference Screw is substantially equivalent to the BioRCI Interference Screw, the Arthrex Screw, the Linvatec Screw. Comparative bench and animal testing demonstrates the equivalence of the HAPLA Interference Screw to the predicate devices.

The Smith & Nephew Suture HAPLA Interference Screw is substantially equivalent to the Smith & Nephew BioRCI Screw, the Arthrex PLA Screw, and the Linvatec BioScrew. These devices are comprised of similar materials and sizes, therefore they are similar in materials, design, and intended use. The only difference between the devices is the addition of the hydroxylapatite. As described in the device description and performance testing section, hydroxylapatite has been used extensively in medical applications particularly in orthopedic implants.

- All of the devices are made from PLA.
- All of the devices are labeled as sterile and are intended for single-use only.
- All of the devices utilize a stainless steel, reusable, non-sterile delivery instrument.
- All of the devices are intended for ACL reconstruction procedures.

Difference

- The HAPLA Interference Screw is manufactured from a blend of PLA and HA whereas the predicate devices are manufactured from PLA only. HA is a widely used material in orthopedic devices such as in orthopedic implants including bone cement, jaw implants, hip implants etc. Testing has shown that the PLA/HA blend is equivalent to PLA screws in mechanical properties and functionality. The addition of HA does not impact safety or effectiveness since HA has a long and extensive history of use in orthopedic implants. The table below summarizes the similarities of the two devices. The similarities in design, materials, intended use, and indications for use between the Smith & Nephew HAPLA Interference Screw and the predicate devices support the claim of substantial equivalence.

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	HAPLA Interference Screw	BioRCI Screw
Implant:		
Product Labeling	Sterile: Single Use Only	Sterile: Single Use Only
Materials	PLA and HA blend	PLA
Indications	ACL/PCL Reconstruction	ACL/PCL Reconstruction
Intended Use	Graft fixation in ACL/PCL Reconstruction	Graft fixation in ACL/PCL Reconstruction
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Instrument:		
Instrument Materials	Stainless Steel	Stainless Steel
Delivery Instrument Sterilization	Non-Sterile: Must be sterilized via steam or ethylene oxide prior to use.	Non-Sterile: Must be sterilized via steam or ethylene oxide prior to use.

Applicant: Todd Doman Date: 24 Jul 00

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 7 2001

Mr. Tedd R. Gosian
Regulatory/Clinical Manager
Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road
Andover, Massachusetts 01810

Re: K002274
Trade Name: HAPLA Interference Screw
Regulatory Class: II
Product Code: HWC
Dated: December 6, 2000
Received: December 7, 2000

Dear Mr. Gosian:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (If Known): K002274

Device Name: Smith & Nephew HAPLA Interference Screw

Indications for Use:

The Smith & Nephew HAPLA Interference Screw is indicated for fixation of bone-tendon-bone or soft tissue grafts during anterior or posterior cruciate ligament reconstruction surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002274

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The-Counter Use No